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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,865	09/28/2000	Erwin Gelfand	2879-68	9468

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/672,865	Applicant(s) GELFAND ET AL.	
	Examiner Janice Li	Art Unit 1632	

-- The MAILING DATE of this communication app ars on the cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

I. Claims 1, 2, 4, 6, 7, 17-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a mammal by administering *in vivo* to said mammal an agent that activates γδ T cells in said mammal, wherein the agent is a protein comprising a BiP-binding motif. Classified in class 514, subclass 2, and class 530, subclass 350.

II. Claims 1, 2, 4, 6, 8, 17-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a mammal by administering *in vivo* to said mammal an agent that activates γδ T cells in said mammal, wherein the agent is a glycosylated protein or peptide. Classified in class 514, subclass 2, and class 530, subclass 395.

III. Claims 1, 2, 4, 6, 9, 17-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a mammal by administering *in vivo* to said mammal an agent that activates γδ T cells in said mammal, wherein the agent is a polyGT or polyGAT, a randomly synthesized heterocopolymeric peptide composed of glutamic acid and tyrosine. Classified in class 514, subclass 2, and class 530, subclass 350.

IV. Claims 1, 2, 4, 6, 10, 17-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a

mammal by administering *in vivo* to said mammal an agent that activates γδ T cells in said mammal, wherein the agent is an oligonucleotide selected from the group consisting of synthetic AT, synthetic GC and other oligonucleotides. Classified in class 514, subclass 44, and class 536, subclass 23.1.

V. Claims 1, 2, 4, 6, 11, 17-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a mammal by administering *in vivo* to said mammal an agent that activates γδ T cells in said mammal, wherein the agent is a mycobacterial product. Classified in class 514, subclass 2, and class 424, subclass 248.1.

VI. Claims 1, 2, 4, 6, 12, 17-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a mammal by administering *in vivo* to said mammal an agent that activates γδ T cells in said mammal, wherein the agent is a *Listeria* cell wall product. Classified in class 514, subclass 2, and class 424, subclass 234.1.

VII. Claims 1, 2, 4, 6, 13, 17-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a mammal by administering *in vivo* to said mammal an agent that activates γδ T cells in said mammal, wherein the agent is a cardiolipin. Classified in class 514, subclass 2, and class 530, subclass 402.

VIII. Claims 1, 2, 4, 6, 14, 17-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a mammal by administering *in vivo* to said mammal an agent that activates γδ T

cells in said mammal, wherein the agent is tumor necrosis factor-alpha. Classified in class 514, subclass 2, and class 424, subclass 85.1.

IX. Claims 1, 2, 4, 6, 15-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a mammal by administering *in vivo* to said mammal an agent that activates γδ T cells in said mammal, wherein the agent is an antibody to γδ T cell receptors. Classified in class 514, subclass 2, and class 424, subclass 130.1.

X. Claims 1, 2, 4, 6, and 17-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising increasing γδ T cell action in a mammal by administering *in vivo* to said mammal an agent that activates γδ T cells in said mammal, wherein the agent is an antibody linked with a compound that activates said γδ T cell. Classified in class 514, subclass 2, and class 424, subclass 178.1.

XI. Claims 1-6, 17-19, and 22-33 are drawn to a method to reduce airway hyper-responsiveness in a mammal, comprising removing γδ T cell from said mammal, inducing said γδ T cells to proliferate *ex vivo*, and returning the cells to the lung tissue of said mammal. Classified in class 424, subclass 93.1.

XII. Claims 34 and 35 are drawn to a method to identify a compound by an *in vitro* method. Classification is to be determined based on the nature of the compound.

XIII. Claim 34 is drawn to a method to identify a compound by an *in vivo* method. Classification is to be determined based on the nature of the compound.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-XI and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are different method for reducing airway hyper-responsiveness in a mammal. The different methods use different agents, which belong to distinct chemical entities. It is noted that these molecules do not share a substantial structural feature essential to a common utility; a person of ordinary skill in the art would not envision one in view of the other. Invention group XI further differs from groups I-X in that it is an ex vivo method for increasing γδ T cell action. The different inventions have different method steps, use different starting materials, which determine that the different method would not share the same mode of operation, and each would have distinct technical considerations.

Inventions XIII and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are different method for screening of compounds, i.e. an *in vitro* vs *in vivo* method. The different inventions use different test criteria to measure the effects of testing compounds, have different method steps, different modes of operation, and have distinct technical considerations.

Inventions X and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (antibody linked with a compound) as claimed does not require the particulars of the subcombination as claimed because the other component in each instance could lend patentability to the combination. The subcombination has separate utility, such as those indicated in groups I-IX.

The differences of the Inventions I-XIII are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Inventions II-VI, IX-XI are directed to a method using materials that belong to patentably distinct species. If one of the inventions II-VI, IX-XIII is elected, further election of a species is necessary. For example, group II embraces a genus of glycosylated protein, group V embraces different mycobacterial products, and group X embraces different combinations of antibody conjugates. If one of the

inventions II-VI, IX-XI is elected, applicant is required to elect a particular product or a combination of product for examination.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Clark can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
April 24, 2002

JAMES KETTER
PRIMARY EXAMINER